

MORVILLO ABRAMOWITZ GRAND IASON & ANELLO P.C.

ELKAN ABRAMOWITZ
RICHARD F. ALBERT
ROBERT J. ANELLO*
KATHLEEN E. CASSIDY
BENJAMIN S. FISCHER
CATHERINE M. FOTI
CHRISTOPHER B. HARWOOD
LAWRENCE IASON
BRIAN A. JACOBS
TELEMACHUS P. KASULIS
KAREN R. KING
THOMAS A. MCKAY
ROBERT M. RADICK*
JONATHAN S. SACK**
EDWARD M. SPIRO
JEREMY H. TEMKIN
RICHARD D. WEINBERG

565 FIFTH AVENUE
NEW YORK, NEW YORK 10017
(212) 856-9600
FAX: (212) 856-9494

www.maglaw.com

WRITER'S CONTACT INFORMATION

charwood@maglaw.com
(212) 880-9547

SENIOR COUNSEL
PAUL R. GRAND

COUNSEL
JASMINE JUTEAU

ROBERT G. MORVILLO
1938-2011

MICHAEL C. SILBERBERG
1940-2002
JOHN J. TIGUE, JR.
1939-2009

* ALSO ADMITTED IN WASHINGTON, D.C.

** ALSO ADMITTED IN CONNECTICUT

August 18, 2023

By ECF

Hon. P. Kevin Castel

Re: *Schottenstein et al. v. Capla et al.*, No. 22-10883-PKC (S.D.N.Y.)

Dear Judge Castel:

I represent defendants Orthogen International GmbH (“Orthogen”), Peter Wehling, Nina Breidenbach, and Peter Niederau (collectively, the “Orthogen Defendants”) in this case, and respectfully submit this renewed pre-motion letter pursuant to Rule 3(A) of Your Honor’s Individual Rules as well as this Court’s order dated July 18, 2023, Dkt. 66 (the “July 18 Order”). The July 18 Order was issued after the Orthogen Defendants and defendants Edward and Yolanda Capla (collectively, the “Caplas”) each separately filed pre-motion letters seeking to dismiss the first amended complaint filed by plaintiffs Douglas Schottenstein and his medical practice, Schottenstein Pain and Neuro, PLLC d/b/a NY Spine (collectively “Plaintiffs”). In response to those pre-motion letters, Plaintiffs sought leave to file a second amended complaint “to address the points raised by both Defendant groups,” Dkt. 65, and, in the July 18 Order, the court granted Plaintiffs the requested leave and set a deadline of August 19, 2023 for both sets of defendants to file renewed pre-motion to dismiss letters.

The second amended complaint filed by Plaintiffs, Dkt. 67 (the “SAC”), fails to cure a single deficiency identified by the Orthogen Defendants in their original pre-motion letter. The SAC sets forth the same defective claims and fails to make the allegations any less conclusory, repetitive, or difficult-to-follow. Thus, for the reasons set forth below — which are the same reasons in Orthogen’s original pre-motion letter — the SAC should be dismissed, this time with prejudice. Plaintiffs now have had three bites at the apple and have confirmed (and re-confirmed) their lack of an actionable claim against the Orthogen Defendants.

As explained in Orthogen’s original pre-motion letter, Plaintiffs’ claims arise out of a 2014 license agreement (the “License Agreement”) between Orthogen (a German biotech company located in Dusseldorf, Germany) as licensor and Dr. Schottenstein and Mr. Capla as licensees. Pursuant to the License Agreement, Dr. Schottenstein and Mr. Capla were permitted to treat patients with Orthogen’s patented Regenokine Program in exchange for their agreement to

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make certain, specified royalty payments to Orthogen. The License Agreement expressly provides that German law governs any dispute between the parties, and it contains an exclusive German forum selection clause, which mandates that “[a]ny dispute arising from or in connection with this Agreement shall be decided exclusively by the competent Courts of Dusseldorf, Germany.” Dkt. 4-2, § 13.2. The clause goes on to repeat the exclusivity of jurisdiction with the Courts of Dusseldorf “for the avoidance of doubt,” and it specifies that the clause applies not only to actions brought by Dr. Schottenstein or Mr. Capla against Orthogen itself, but also to “any and all actions brought by any of the Licensees [Dr. Schottenstein or Mr. Capla] against any employee of the Licensor [Orthogen] and/or any other third party acting on behalf or in the interest of the Licensor in connection with this Agreement, including . . . any . . . representative of Orthogen.” *Id.*

Plaintiffs’ SAC, like their Amended Complaint, fails to comply with the basic requirements of Federal Rule of Civil Procedure 8, in that it lacks “a short and plain statement of the grounds for the court’s jurisdiction” and “of [each] claim showing that [Plaintiffs’ are] entitled to relief.” Fed. R. Civ. P 8(a)(1)-(2). Setting aside the Rule 8 defects — which persist even after Plaintiffs were put on notice of them — the SAC asserts breach of contract and various other claims against the Orthogen Defendants based on two allegations that are pled in wholly conclusory fashion: namely, that Orthogen (i) supposedly lacks justification to treat the License Agreement as having been terminated as of May 2020, and (ii) entered into a new license agreement with Mr. Capla (and Mr. Capla’s brother-in-law) purportedly “in order to avoid the likelihood of regulation of Regenokine by the FDA.” SAC ¶ 64; *see, e.g., id.* ¶¶ 50-52.

In addition to asserting claims against the Orthogen Defendants that lack well-pled factual support, the SAC, like Plaintiffs’ two complaints before it, also attempts to manufacture federal question jurisdiction (and to avoid the License Agreement’s exclusive German forum selection clause) by naming the FDA as a defendant, and asking this Court to issue a declaratory judgment regarding whether the Regenokine Program is subject to FDA regulation. Specifically, without providing any type of reasoned explanation for why the Regenokine Program even plausibly could be subject to FDA regulation, Plaintiffs ask this Court to issue a declaratory judgment confirming that (i) the Regenokine Program is *not* subject to FDA regulation and (ii) Dr. Schottenstein’s past administration of the Regenokine Program therefore does *not* subject him to liability. *E.g., id.* ¶ 18, 36, 191. Notably, the declaratory relief that Plaintiffs seek flatly is inconsistent with Plaintiffs’ (unsupported and incorrect) suggestion that Orthogen terminated the License Agreement supposedly “to avoid the *likelihood* of regulation of Regenokine by the FDA, *id.* ¶ 64 (emphasis added), or their (equally conclusory and incorrect) assertion that “a *likely* basis for federal oversight” exists, *id.* ¶ 11 (emphasis added).

Plaintiffs’ claims should be dismissed as to the Orthogen Defendants for at least three independent reasons. *First*, New York is not the proper forum for Plaintiffs’ claims, because the claims all arise from the License Agreement, which contains an exclusive German forum selection clause in favor of all Orthogen Defendants, and the claims thus should be dismissed under Rule 12(b)(3). Consistent with the exclusive German forum selection clause, shortly before Plaintiffs filed this case on December 27, 2022, Orthogen filed a civil action against Dr. Schottenstein in Germany on December 21, 2022, in which Orthogen seeks the reverse of what

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Plaintiffs seek here: a declaration that the License Agreement properly is treated as having been terminated as of May 2020.¹ The dispute underlying Plaintiffs' claims thus can (and should) be decided in the context of the pending German proceeding. *Second*, Plaintiffs' claims should be dismissed under Rule 12(b)(1), because (i) Plaintiffs' declaratory judgment claim is not cognizable (among other defects, Plaintiffs lack standing to pursue it), and (ii) Plaintiffs still have not pled facts sufficient to establish diversity jurisdiction (despite the Orthogen Defendants having identified the specific defect in Plaintiffs' diversity allegations in their prior pre-motion letter, *see* Dkt. 62 at 6 & n.5).² *Finally*, Plaintiffs' claims should be dismissed under Rule 12(b)(6) because Plaintiffs have not pled facts sufficient to sustain any of their claims.

A. Plaintiffs' Claims Against the Orthogen Defendants Must Be Dismissed Because They Arise Out of the License Agreement, which Contains an Exclusive German Forum Selection Clause

The License Agreement's German forum selection clause requires dismissal of all Plaintiffs' claims against the Orthogen Defendants. A forum selection clause presumptively is enforceable when, as here, (i) the clause was reasonably communicated to the opposing party, (ii) the clause is mandatory and not permissive, and (iii) the opposing party's claims are subject to the clause. *Phillips v. Audio Active Ltd.*, 494 F.3d 378, 383 (2d Cir. 2007). When, as here, a forum selection clause meets the foregoing requirements, the clause will be enforced unless the opposing party "make[s] a sufficiently strong showing that 'enforcement would be unreasonable or unjust, or that the clause was invalid for such reasons as fraud or overreaching.'" *Id.* at 383-84 (citation omitted).

Here, the German forum selection clause meets the above requirements because it (i) is contained in an agreement to which Dr. Schottenstein was a party and that he signed (and thus reasonably was communicated to Plaintiffs), (ii) broadly states that the Courts of Dusseldorf have "exclusive[] jurisdiction over "[a]ny dispute arising from or in connection with this Agreement," including any claims brought by "any of the Licensees against any employee of the Licensor" (and thus is mandatory), *see* Dkt. 4-2, § 13.2, and (iii) covers both Plaintiffs' breach of contract and other claims, because the other claims all arise out of the License Agreement (with the impetus and/or premise of all the claims being Plaintiffs' assertion that Orthogen lacks sufficient grounds to treat the License Agreement as having been terminated as of May 2020). *See* SAC ¶¶ 193-240, 248-71. *See also New York Marine & Gen. Ins. Co. v. M/V Admiralenengracht*, 1999 WL 253628, at *2 (S.D.N.Y. Apr. 28, 1999) (upholding forum selection clause as mandatory because, as here, it stated that the designated forum was the "exclusive" forum); *Bluefire Wireless, Inc. v. Cloud9 Mobile Commc'ns, Ltd.*, 2009 WL 4907060, at *3 (S.D.N.Y. Dec. 21, 2009) (finding tort claims to be covered by forum selection clause when, as

¹ Plaintiffs acknowledge that, by letter dated November 28, 2022, Orthogen notified them of its intent to file the referenced civil action in Germany. *See* SAC ¶ 133.

² Moreover, Plaintiffs' claims should be dismissed against the individual Orthogen Defendants (who Plaintiffs acknowledge all "maintain[] an address" with Orthogen in Germany, *see* SAC ¶¶ 65, 69, 74) because the SAC fails to allege that any of them had sufficient contacts with this jurisdiction to support the exercise of personal jurisdiction over them.

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here, the “tort claims ultimately depend on the existence of a contractual relationship between the parties, or if the resolution of the claims relates to interpretation of the contract, or if the tort claims involve the same operative facts as a parallel claim for breach of contract”).

Plaintiffs cannot avoid enforcement of the German forum selection clause because, under the circumstances here, enforcement of the clause would not be unreasonable or unjust. As an initial matter, the unreasonable/unjust exception “is construed narrowly” and applies only in “limited circumstances” that are not present here, such as when “due to the grave inconvenience or unfairness of the selected forum,” enforcement of the clause would “deprive [the opposing party] of his day in court.” *Koninklijke Philips Elecs. v. Digital Works, Inc.*, 358 F. Supp. 2d 328, 332 (S.D.N.Y. 2005). When, as here, sophisticated parties to a contract agree to an exclusive German forum selection clause, courts enforce the parties’ agreement.³ See, e.g., *K.K.D. Imports, Inc. v. Karl Heinz Dietrich GmbH & Co. Int’l Spedition*, 36 F. Supp. 2d 200, 204 (S.D.N.Y. 1999) (enforcing German forum selection clause); *Jockey Int’l, Inc. v. M/V Leverkusen Express*, 217 F. Supp. 2d 447, 457 (S.D.N.Y. 2002) (same).

In arguing against enforcement, Plaintiffs raise three meritless arguments: that they will be unable to pursue their claims in Germany because (i) a German court would not have jurisdiction over their declaratory judgment claim, (ii) the forum selection clause bars their non-declaratory judgment claims, and (iii) their non-declaratory judgment claims are “outside the scope of the License Agreement.” E.g., SAC ¶¶ 6, 10, 277, 281-83. As an initial matter, “the potential unavailability of certain claims, or even the entire action, in the selected forum is insufficient to make the forum-selection clause unreasonable or unjust,” *Kasper Glob. Collection & Brokers, Inc. v. Glob. Cabinets & Furniture Mfrs. Inc.*, 952 F. Supp. 2d 542, 565 (S.D.N.Y. 2013). In any event, Plaintiffs’ arguments fail because: (i) as demonstrated below, the declaratory judgment claim is not cognizable; (ii) contrary to Plaintiffs’ assertion, the forum selection clause does not bar any claim, and instead, broadly authorizes (and requires) Dr. Schottenstein to bring in Germany “[a]ny dispute from or in connection with this Agreement,” and “[f]or the avoidance of doubt,” the clause specifies that such disputes include “any and all actions by any of the Licensees against any employee of the Licenser,” Dkt. 4-2 at § 13.2; and (iii) also contrary to Plaintiffs’ assertion, Plaintiffs’ claims all fall within the scope of the License Agreement because they all depend on, and thus arise out of, Dr. Schottenstein’s status as a former Regenokine Program licensee under the License Agreement. Moreover, no impediment exists to Plaintiffs pursuing fraud, breach of contract, or tort claims against Orthogen in Germany (however meritless such claims may be).

As a final matter, litigating in Germany certainly would not be unduly burdensome for, or otherwise unfair to, Dr. Schottenstein when (i) he admits that he and Mr. Capla each received “nearly \$2 million per year” for at least six years (from at least 2014 through 2020) for administering the Regenokine Program, SAC ¶ 83; see *id.* ¶ 27, and (ii) over the course of his

³ Notably, the 2014 License Agreement was the third license agreement that Dr. Schottenstein entered with Orthogen, and like the 2014 Agreement, the predecessor agreements also (i) required Dr. Schottenstein to pursue any claims that he might assert against Orthogen in Germany and (ii) provided that German law would apply to any such claims.

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eight years administering the Regenokine Program (from 2012 through 2020), he repeatedly executed license agreements with Orthogen (a German company) containing the German forum selection clause, *see supra* n.3. The above-referenced factual admission that Dr. Schottenstein and Mr. Capla each received “nearly \$2 million per year,” as well as Plaintiffs’ related admission that Dr. Schottenstein and Mr. Capla administered the Regenokine Program “to as many as 3,500 patients,” SAC ¶ 83, mean that Dr. Schottenstein and Mr. Capla failed to pay Orthogen millions of dollars in royalties to which Orthogen was due under their Regenokine Program license agreements. Those admissions (which Plaintiffs now have repeated several times here, even after Orthogen put them on notice of the allegations’ significance) are the basis for separate petitions that Orthogen has filed under 28 U.S.C. § 1782 seeking discovery from Plaintiffs and Mr. Capla in anticipation of filing a civil action against them in Germany (consistent with the forum selection clause in their license agreements) based on their apparent historical underpayment of royalties to Orthogen. *See* Dkt. 25 (explaining why Dr. Schottenstein’s foregoing admissions reflect that (i) Orthogen wrongly was deprived of millions of dollars in royalty payments and (ii) support Orthogen’s separate petitions for Section 1782 discovery). That Orthogen is complying with the requirements of the parties’ German forum selection clause — and availing itself of its right under Section 1782 to seek discovery from Plaintiffs and Mr. Capla in anticipation of pursuing claims against them in Germany — does not somehow render the forum selection clause unenforceable in connection with Plaintiffs’ distinct claims in this action (as Plaintiffs wrongly appear to suggest, e.g., SAC ¶ 282).

Finally, even if true, that Dr. Schottenstein (with his education and substantial means) chose not to consult counsel in repeatedly agreeing to the forum selection clauses, SAC ¶ 7; *see supra* n.3, is irrelevant. *See Martin v. Creative Mgmt. Grp., Inc.*, 2010 WL 2629580, at *2 (S.D.N.Y. June 29, 2010) (rejecting argument that forum selection clause was unenforceable because the plaintiff “was not represented by an attorney in the negotiation or drafting of the Agreement”). Accordingly, Plaintiffs’ claims against the Orthogen Defendants must be dismissed under Rule 12(b)(3) in favor of the pending German proceeding — which, as noted above, addresses the same issue underlying the non-declaratory judgment claims that Plaintiffs have asserted here: whether the License Agreement properly is treated as having been terminated as of May 2020. Moreover, given the enforceable German forum selection clause (and the parties’ related agreement that German law governs the parties’ dispute), no basis exists for Plaintiffs’ request that this Court issue an order precluding Orthogen from adjudicating its dispute with Dr. Schottenstein regarding the termination of his Regenokine Program license in the pending German proceeding. *See* SAC ¶¶ 272-85.

B. Plaintiffs’ Claims Against the Orthogen Defendants Also Fail Because Plaintiffs Have Failed to Allege a Sufficient Basis for Subject Matter Jurisdiction

Plaintiffs’ claims also should be dismissed because they have not alleged a sufficient basis for this Court’s exercise of either federal question jurisdiction or diversity jurisdiction. Plaintiffs attempt to manufacture federal question jurisdiction through their (fundamentally flawed) declaratory judgment claim. In asking this Court to issue a declaratory judgment that the Regenokine Program is not subject to FDA regulation, Plaintiffs, in effect, seek to have this Court (i) review the FDA’s (appropriate) inaction to date with respect to the Regenokine

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Program and (ii) confirm (consistent with the FDA’s appropriate inaction) that the Regenokine Program does not require FDA approval. *E.g.*, Am Compl. ¶¶ 166, 191.⁴ Plaintiffs’ declaratory judgment claim is not cognizable for at least four independent reasons.

First, even after the Orthogen Defendants pointed out in their prior pre-motion letter that Plaintiffs had not identified any statute (or other law) creating a right to seek judicial review of the FDA’s inaction with respect to the Regenokine Program, Plaintiffs still have not done so, thus confirming what is demonstrated below: that no such law exists. *See Cnty. of Suffolk, N.Y. v. Sebelius*, 605 F.3d 135, 140 (2d Cir. 2010) (“unequivocally expressed statutory waiver” required for a court to review agency conduct); *see generally* 33 Wright & Miller, Fed. Prac. & Proc. § 8301 (“[t]o challenge an agency action in court, a plaintiff must invoke some law creating and defining a right to seek judicial review”).

Second, the only law that even conceivably could create a right to seek judicial review of the FDA’s inaction with respect to the Regenokine Program is the Administrative Procedure Act (the “APA”), but the prerequisites for review under the APA plainly have not been met here. Judicial review under the APA is limited to a “final agency action.” 5 U.S.C. § 704. Although a “final agency action” can include a decision not to take action, *see Heckler v. Chaney*, 470 U.S. 821, 828 (1985), here, Plaintiffs do not point to any FDA decision pertaining to the Regenokine Program, much less a final decision not to take the action Plaintiffs are seeking — *i.e.*, to expressly state (what both Plaintiffs and Orthogen rightly believe to be the case) that the Regenokine Program is not subject to FDA regulation. For this additional reason, the declaratory judgment claim must be dismissed. *See Bannister v. U.S. Treasury Dep’t*, 2021 WL 4443020, at *5 (S.D.N.Y. Sept. 28, 2021) (dismissing action because the plaintiffs had “not alleged a final agency action as required to assert a valid APA claim”).

Third, even if the FDA had made a final decision not to take the action Plaintiffs are seeking, the declaratory judgment claim still would fail, because such a decision would not be subject to judicial review. Under settled law, the FDA’s decision not to exercise its “investigative or enforcement” authority over the use of a drug or treatment is not subject to judicial review. *See, e.g., Heckler*, 470 U.S. at 837-38 (1985); *Jerome Stevens Pharms., Inc. v. Food & Drug Admin.*, 402 F.3d 1249, 1257 (D.C. Cir. 2005).

Finally, Plaintiffs lack standing to pursue their declaratory judgment claim, because they have not alleged a cognizable injury sufficient to support the claim, *i.e.*, “[a]n injury [that is] . . . concrete and particularized and actual or imminent.” *Susan B. Anthony List v. Driehaus*, 573

⁴ Plaintiffs suggest incorrectly that this Court has made a determination supportive of federal question jurisdiction. Specifically, Plaintiffs assert that “[t]his Court, in determining the treatment had been utilized for a number of years, narrowed the Federal Question for which Plaintiffs respectfully request declaratory relief: . . .,” SAC ¶ 166, and that “[t]his Honorable Court decided [that Plaintiffs] have the right to know if Regenokine is subject to US FDA regulation, *id.* ¶ 167. This Court, of course, has made no determinations in this case, but has (flatly contrary to Plaintiffs’ suggestion) expressed skepticism as to the existence of federal question jurisdiction. *See* Dkt. 23 (“The Court remains dubious about the existence of either federal question or diversity jurisdiction at the time that this action was commenced.”).

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U.S. 149, 157-58 (2014). Instead, Plaintiffs point only to (i) their supposed concern for the “general public,” *see, e.g.*, SAC ¶ 187, which not only is insufficient as a matter of law to confer standing, *see Gill v. Whitford*, 138 S. Ct. 1916, 1931 (2018), but also is inconsistent with Dr. Schottenstein’s prior administration of the Regenokine Program for “a decade,” *see* SAC ¶ 16; and (ii) their supposed concern that they may face liability due to their prior administration of the Regenokine Program, *see, e.g.*, SAC ¶¶ 167, 182, which also is insufficient because Plaintiffs have not alleged any threatened enforcement action against them or any other fact that could support an inference that they face a concrete and particularized threat of enforcement (which, of course, they do not, because, as is evident from the declaratory relief they are seeking, they, like Orthogen, rightly agree that the Regenokine Program is not subject to FDA regulation),⁵ *see, e.g.*, *Does 1-10 v. Suffolk Cnty.*, 2022 WL 2678876 (2d Cir. July 12, 2022) (no standing where threat of enforcement action insufficiently alleged); *Adam v. Barr*, 792 F. App’x 20, 22-23 (2d Cir. 2019) (same).

Because Plaintiffs cannot establish federal question jurisdiction through their declaratory judgment claim, the SAC must be dismissed unless it alleges facts sufficient to establish that the current parties to this action were diverse at the time Plaintiffs filed their initial Complaint. *See Grupo Dataflux v. Atlas Glob. Grp., L.P.*, 541 U.S. 567, 570-71 (2004) (diversity of parties evaluated as of the date the case was filed). Although Plaintiffs claim that they are diverse from the Caplas due to the Caplas’ alleged Florida domicile, SAC ¶¶ 1, 76, neither the initial Complaint, the Amended Complaint, nor the SAC alleges where the Caplas were domiciled *at the time the initial Complaint was filed*. Thus, Plaintiffs have not carried their burden to establish diversity jurisdiction.

In their prior pre-motion letter, the Orthogen Defendants identified this issue and noted their understanding that, unlike the other deficiencies in the Amended Complaint, Plaintiffs’ failure to plead facts sufficient to establish diversity jurisdiction was curable. Dkt. 62 at 6 n.5. Amazingly, despite being given a roadmap for how to cure the defect, *see id.* at 6, and explicitly stating that they were seeking to amend their complaint again to “address the points raised by [the defendants],” Dkt. 65, Plaintiffs failed to cure in the SAC the one deficiency they presumably could have fixed.

C. Plaintiffs’ Claims Against the Orthogen Defendants Also Fail Because the SAC Lacks Sufficient Allegations to Support Them

Finally, the claims against the Orthogen Defendants also should be dismissed because the SAC lacks sufficient allegations to support them. As an initial matter, the breach of contract claim fails because the SAC ignores that, under the governing German law, ample undisputed and indisputable facts exist to justify Orthogen’s treatment of the License Agreement as having

⁵ In support of their declaratory judgment claim, Plaintiffs make only conclusory assertions — which unsurprisingly are devoid of any well pled factual support — including that (i) Orthogen supposedly “bar[s]” U.S. doctors from inquiring about whether the Regenokine Program is subject to FDA regulation, SAC ¶ 11, and (ii) Dr. Schottenstein supposedly “pressed the issue of whether Regenokine should undergo [FDA] regulation,” *id.* ¶ 51.

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been terminated as of May 2020. Indeed, Plaintiffs' SAC (like their prior pleadings) cites correspondence from Orthogen that identifies such facts, and Plaintiffs continue not to address the facts, much less dispute them. *See SAC ¶ 132* (citing November 28, 2022 letter from Orthogen's counsel).

Moreover, whether under German or U.S. law, Plaintiffs' remaining claims against the Orthogen Defendants also fail to state a claim, including because: (i) they all arise from the same facts (and seek the same damages) as the breach of contract claim and thus cannot be pursued in addition to (or in lieu of) the breach of contract claim, *see Shaub & Williams, L.L.P. v. Augme Techs., Inc.*, 2014 WL 625390, at *3 (S.D.N.Y. Feb. 14, 2014) (under such circumstances, denying leave to amend to add tort claims because they were duplicative of breach of contract claim); *see also Havell Cap. Enhanced Mun. Income Fund, L.P. v. Citibank, N.A.*, 84 A.D.3d 588 (1st Dep't 2011) (dismissing fraud and other claims as duplicative of breach of contract claim); and (ii) Plaintiffs have not pled facts sufficient to establish one or more elements of the claims (such as the claim for tortious interference, which requires "the existence of a contract between plaintiff and a third party," *Kronos, Inc. v. AVX Corp.*, 81 N.Y.2d 90, 94 (1993), which Plaintiffs have not alleged). Finally, at least some of the remaining claims are not cognizable under any circumstances (like the claim for "civil conspiracy," *see Valentini v. Grp. Health Inc.*, 2021 WL 6113991, at *7 (S.D.N.Y. Dec. 27, 2021) (no independent cause of action for "civil conspiracy")) or plainly are inapplicable even under the most charitable reading of the SAC (like the claims for an accounting, *see Roslyn Union Free Sch. Dist. v. Barkan*, 16 N.Y.3d 643, 653 (2011) (accounting claim only applicable to stolen funds, which is not alleged here) and a constructive trust, *Simonds v. Simonds*, 45 N.Y.2d 233, 241 (1978) (constructive trust claim requires, among other things, a fiduciary relationship and a transfer in reliance on a promise, none of which is alleged here)).

* * *

Accordingly, for the reasons stated herein, the claims against the Orthogen Defendants in Plaintiffs' SAC should be dismissed with prejudice.

Respectfully submitted,

/s/ Christopher B. Harwood
Christopher B. Harwood

cc: all parties (by ECF)